

REMARKS

1. Claim Amendments

In claim 227 the amendments specify that the apparatus includes a main chamber, a residence chamber and an airlock, and that a communication port is located between the main chamber and a residence chamber and thus is not the airlock.

Basis for the amendments of claim 227 is in the WO-document on page 47, lines 25-28 in respect of the airlock; and in respect of the communication port it is simply specified that the two chambers which is described in claim 227 is the main chamber and residence chambers.

Claims 242-243 have been rewritten as proper method claims, based on page 1 lines 6-14. Hence, the rejection under 35 USC 112 should be overcome.

Claim 244 is a new method-of-use claim based on page 5, lines 23-32.

2. Non-Art Rejections (OA pp. 9-10)

Claims 242 and 243 have been amended to recite a method of using the system of claim 227 which includes one or more positive active steps.

3. Prior Art Rejections

3.1. Claims 227, 228, 231, 234, 235, 237 and 238 stand rejected as obvious over Findley (USP 4,892,830; 1990) in view of Lindenberg (WO 99/67365) and Ellington (USP 6,140,121; 2000).

Amended claim 227 describes a main chamber with an airlock and at least one residence chambers located inside or connected to the main chamber. The oxygen tension of the main chamber and the at least one residence chambers can be regulated independently.

The invention is non-obvious in respect to the art relied on by the Office Action of 22 October 2008 for the reasons presented below.

**Findley et al (US 4,892,830)**

Findley et al describes an environmentally controlled incubator ("main chamber") having an airlock and a storage compartment. The incubator includes sensors for determining the oxygen and carbon dioxide concentration within the chamber and means for adding carbon dioxide, nitrogen or oxygen to the ambient gas within the incubator in order to maintain the desired levels of carbon dioxide and oxygen.

The Examiner initially states that the "main chamber" 13 and "airlock" 57 as described by Findley et al are the "main chamber" and the "residence chamber" of the invention described in the present patent application and that the oxygen tension may be changed independently in these two chambers (Office Action page 2 bottom). However, the Examiner also states that the "residence chamber" of the present patent application is the "storage compartment" 68 of Findley et al (Office Action page 3 top).

Amended claim 227 specify the existence of a main chamber, a residence chamber and an air-lock, as separate entities, hereby only the "storage compartment" of Findley et al can be compared with the "residence chamber" of the present claim.

Findley et al when referring to Fig. 5-6 describes that "an interior platform and storage compartment 68 may be provided within the chamber 13 to the right of the microscope stage 25 for providing additional storage space for culture dishes and other items within the chamber 13. Preferably the top surface 76 of the platform 77 is at the same height as that of the microscope stage 25. The hinged top sections 78 of the platform 77 may be opened for access to the interior storage compartment. Apertures in the side walls 79 and 80 of the platform 77 permit circulation of gas through the interior of the platform for maintaining appropriate storage conditions" (column 7, lines 27-40).

From the above quotation it can be seen that the oxygen tension of the storage compartment is the same as in the chamber 13 i.e. of the main chamber as "apertures in the side walls 79 and 80 of the platform 77 permit circulation of gas through the

interior of the platform for maintaining appropriate storage conditions". In Fig. 6 it is clearly indicated by arrows that the air can circulate through the apertures of the side walls 79 and 80. Thus when having air circulating from the chamber 13 (main chamber) and through the storage compartment 68 these chambers are not independently regulated in respect of the oxygen tension.

The invention of the present patent application is a system with an apparatus having a main chamber and one or more residence chambers located inside or attached to the main chamber. All of these chambers can be regulated independently in respect of oxygen tension. Also the apparatus has an airlock distinct from these chambers.

**Lindenberg et al (WO99/67365)**

The document describes a method for in vitro maturation of a human gamete by culturing an immature human gamete in a chemically defined cell culture medium. It is described that the immature oocytes are aspirated transvaginally with a 17 g Cook needle (page 11, line 5). Some culturing conditions are also described e.g. 5% CO<sub>2</sub>.

The document does not describe the physical apparatus for in vitro producing a mammalian pre-embryo.

**Ellington et al (US 6,140,121)**

The document describes methods and compositions to improve germ cell and embryo survival and function. Use of different compounds and different methods in the process of obtaining motile sperm having improved function are described.

In the process of washing or isolating a sperm sample it is described that sperm are isolated by a swim-up method by which sperm are layered in wash medium using a 27 gauge needle (column 14, lines 44-55).

The document does not describe the physical apparatus for in vitro producing a mammalian pre-embryo

**Conclusion in respect of Findley et al, Lindenberg et al and Ellington et al**

The documents of Findley et al, Lindenberg et al and Ellington et al do not when taken together describe a system of claim 227, as these documents do not describe an apparatus with a main chamber, at least one residence chamber and an air lock, where the oxygen tension of the main chamber and the at least one residence chamber are independently changed.

Thus it is not obvious for the person skilled in the art to invent the invention as described in amended claim 227 of the present patent application.

3.2. Claim 229 is rejected as obvious over the "227" art in view of Burkman (1988).

**Burkman et al** describes a microperfusion chamber for study of mammalian spermatozoa. A population containing as few as several hundred sperm cells may be observed in the chamber during successive changes of the suspending medium as controlled by a perfusion pump. The percentage of motile cells, linear swimming speed and incidence of hyperactivated motility are reported. In the washing process it is described that pH increased due to loss of CO<sub>2</sub>, and it is proposed to use a gas tight syringe to eliminate the problem (page 106, Experiment 3).

3.3. Claims 230, 232 and 233 are rejected as obvious over the "227" art in view of Orchard, USP 5,169,217.

**Orchard et al** describes a controlled environment chamber apparatus for maintaining biological material under controlled conditions of temperature and/or humidity comprises a cabinet defining a chamber, a door for controlling access to the chamber, and a clean air source for providing a flow of clean air past the chamber opening (the abstract).

3.4. Claim 236 is rejected as obvious over the "225" [sic, "227"] art in view of Ranoux, USP 6,050,935.

**Ranoux et al** describes a container assembly for intravaginal fertilization and culture and embryo transfer and method of intravaginal fertilization and culture employing such a container. Described is an intra-vaginal fertilization and culture container in which embryos may be easily located and inspected microscopically in situ and which enables the subsequent transfer directly from the container to the uterine cavity by means of a catheter or the like (column 2, lines 53-58). It is also described that the container has a main chamber and an microchamber adapted to collect one or more embryos for microscopic inspection and/or retrieval (column 3, lines 27-34) and that the material should be CO<sub>2</sub> permeable (column 5, line 14).

3.5. Claims 239 and 240 are rejected over the 227 art in view of Vajta, USP 6,399,375.

**Vajta** describes a method and apparatus for culturing cells and tissues. The apparatus being an incubator comprises a tank to be filled with a liquid. The incubator also has a cover. Flexible bags etc with cell cultures can be located within the incubator and heated by heating the liquid of the incubator. The flexible bags can be supplied with preheated gas mixture (paragraph 40 and 41).

3.6. Claim 241 is rejected as obvious over the 227 art in view of Campbell, US Pub. 2002/0068358.

Campbell teaches a computer-controlled support assembly.

3.7. None of the additional documents (Burkman, Orchard, Ranoux, Vajta, Campbell) overcome the deficiency of the "227" art, i.e., none of them teach a system with a main chamber and a residence chamber wherein the oxygen tension of these chambers can be independently regulated. Thus, claim 227 is non-obvious.

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It follows that all claims dependent on 227 are also non-obvious.

Respectfully submitted,

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